UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/821,573	04/08/2004	Michel Gilbert	019633-000128US	2448

20350 7590 04/20/2006

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
SWOPE, SHERIDAN	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 04/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/821,573	GILBERT ET AL.	
	Examiner	Art Unit	
	Sheridan L. Swope	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *amdt of April 8, 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *43-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 April 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *0404*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendment of April 8, 2004, canceling Claims 1-42 and adding Claims 43-46, is acknowledged. Claims 43-46 are pending. Claims 43-46 constitute a single invention, encompassing a recombinant polypeptide with α-2,3-sialytransferase activity, and are hereby examined.

Priority

The priority date of the instant invention is taken to be February 1, 1999, the filing date of US 60/118,213.

Drawings

Figure 3, discloses sequence(s) that are not identified by a sequence identifier number (SEQ ID NO:). The sequence rules embrace all nucleotide sequences with ten or more bases and all amino acid sequences with four or more amino acids. Said sequences must be disclosed in a sequence listing and identified by a specific SEQ ID NO: (MPEP 2421.02). 37 CFR 1.821(d) requires the use of the assigned sequence identifier number in all instances where the description or claims of a patent application discuss sequences, regardless of whether a given sequence is also embedded in the text of the description or claims of an application. Applicant is required to correct Figure 3, or the legend thereto, to identify all of the sequences disclosed therein by sequence identifier numbers.

Information Disclosure Statement

Parts of the Information Disclosure Statement filed April 8, 2004 fail to comply with 37 CFR 1.98(a)(1). Copies of initialed Information Disclosure Statements and Examiner provided 892 forms from other applications do not comply with 37CFR 1.98(a)1 (MPEP 609.05(a)(b)). The Information Disclosure Statement has been placed in

the application file, but the information referred to therein has not been considered. If Applicants wish for the references therein to be considered, a supplemental Information Disclosure Statement should be submitted.

Specification-Objections

The first paragraph of the specification should be updated to reflect the status of all priority documents.

The specification is objected to for containing hyperlinks. USPTO policy does not permit the USPTO, i.e, via an issued patent, to link to any commercial sites, since the USPTO exercises no control over the organization, views or accuracy of the information contained on these outside sites. Hyperlinks and other forms of browser-executable code, especially commercial site URLs, are not to be included in a patent application. (MPEP 608.01) The specification should be carefully checked and all URLs removed.

The specification is objected to because at page 57, paragraph 3, it is stated that Table 4 shows the results for NMR analysis of the reaction products produced by ORF #7a, designated cst-II. However, Table 4 fails to disclose any data labeled "ORF #7a" or "cst-II".

Claims-Objections

Claim 45 is objected to because the phrase "polynucleotide sequence", on line 2 and again on lines 2-3, lacks antecedent basis. For purposes of examination, it is assumed that said phrase is meant to refer back to "nucleic acid" on line 5 of Claim 43.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Double Patenting

> The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).
> A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Claims 43-46 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 13-20 and 43-45 of US Application 10/303,161 as well as Claims 43-46 and 51 of US Application 10/821,604. Although the conflicting claims are not identical, they are not patentably distinct from each other. Claims 43-46 herein and the claims of 10/303,161 and 10/821,604 are all directed to polypeptides comprising a sequence having α-2,3-sialyltransferase activity, wherein the sequence is set forth by SEQ ID NO: 3 herein, is encoded by SEQ ID NO: 2

herein, and/or is encoded by a polynucleotide that can be generated by PCR using the oligonucleotides set forth by SEQ ID NO: 46 and 47 herein. Specifically, 10/303,161 recites the polypeptide of SEQ ID NO: 3 therein, while 10/821,604 recites a polypeptide comprising a sequence having α-2,3-sialyltransferase activity, wherein the sequence is encoded by a polynucleotide that can be generated by PCR using the oligonucleotides set forth by SEQ ID NO: 40 and 41 therein. The claims differ in that Claims 43-46 herein also recite polypeptides comprising a sequence having both α-2,3-sialyltransferase and α-2,8-sialyltransferase activity, while 10/303,161 also recites polypeptides comprising a sequence having at least 80% identity to SEQ ID NO: 3 therein as well as sequences having homology to SEQ ID NO: 5 and 7 therein, while 10/821,604 also recites polypeptides comprising a sequence having β1,3-galactosyltransferase or β1,4-N-acetylglucosaminyl transferase activity. The portions of the specifications in the above applications that support the recited polypeptides includes embodiments that would anticipate Claims 43-46 herein, e.g., polypeptides comprising a sequence having α-2,3-sialyltransferase, wherein the sequence is set forth by SEQ ID NO: 3, is encoded by SEQ ID NO: 2, or is encoded by a polynucleotide that can be generated by PCR using the oligonucleotides set forth by SEQ ID NO: 46 and 47, which are also the polypeptides specifically recited in the claims of the above listed applications. Claims 43-46 herein cannot be considered patentably distinct over the claims of the above listed patents and applications when there are specifically recited embodiments (polypeptides comprising a sequence having α-2,3-sialyltransferase, wherein the sequence is set forth by SEQ ID NO: 3, is encoded by SEQ ID NO: 2, or is encoded by a polynucleotide that can be generated by PCR using the oligonucleotides set forth by SEQ ID NO: 46 and 47) that

would anticipate Claims 43-46 herein. Alternatively, Claims 43-46 herein cannot be considered patentably distinct over the claims of the above applications when there are specifically disclosed embodiments in those applications that supports the claims recited therein and falls within the scope of Claims 43-46 herein, because it would have been obvious to a skilled artisan to modify the scope of the polypeptides recited in said applications by selecting specifically disclosed embodiments that supports those claims, i.e., polypeptides comprising a sequence having α-2,3-sialyltransferase, wherein the sequence is set forth by SEQ ID NO: 3, is encoded by SEQ ID NO: 2, or is encoded by a polynucleotide that can be generated by PCR using the oligonucleotides set forth by SEQ ID NO: 46 and 47 herein. One having ordinary skill in the art would have been motivated to do this, because such embodiments are disclosed as being a preferred embodiment within the prior patents and applications.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112-Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 43-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 43 is indefinite in the recitation of "amplified by PCR" as this term is unclear absent a statement of the conditions under which the PCR reaction is preformed. Polynucleotides that will be generated under some PCR conditions, will not necessarily be generated under different conditions. Neither the

specification nor the claims define the conditions under which the PCR of Claim 43 is performed or the DNA template to be used. Thus, Claim 43 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite because the skilled artisan would not know the metes and bounds of the recited invention. Since, Claims 44-46 are dependent on Claim 43, said claims are also rejected under 35 U.S.C. 112, second paragraph, for the same reasons. For purposes of examination, it is assumed that the PCR reaction is performed under any conditions with any DNA template.

Claim Rejections - 35 USC § 112-First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claims 43, 44, and 46 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the polypeptide of SEQ ID NO: 3, as encoded by the polynucleotide of SEQ ID NO: 2, does not reasonably provide enablement for any polypeptide comprising any sequence wherein the sequence has α-2,3-sialyltransferase and is encoded by any polynucleotide that can be generated by PCR using the oligonucleotides set forth by SEQ ID NO: 46 and 47. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In regards to this enablement rejection, the application disclosure and claims are compared per the factors indicated in the decision In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). These factors are considered when determining whether there is

sufficient evidence to support a description that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. The factors include but are not limited to: (1) the nature of the invention; (2) the breath of the claims; (3) the predictability or unpredictability of the art; (4) the amount of direction or guidance presented; (5) the presence or absence of working examples; (6) the quantity of experimentation necessary; (7) the relative skill of those skilled in the art. Each factor is here addressed on the basis of a comparison of the disclosure, the claims, and the state of the prior art in the assessment of undue experimentation.

Claim 43 is so broad as to encompass any polypeptide comprising any sequence having α-2,3-sialytransferase activity, wherein the sequence is encoded by any polynucleotide that can be generated by PCR using the oligonucleotides of SEQ ID NO: 46 and 47, wherein the PCR is performed under any conditions with any DNA template. Claim 44 is so broad as to encompass any polypeptide comprising any sequence having dual α-2,3-sialytransferase/α-2,8-sialytransferase activity, wherein the sequence is encoded by any polynucleotide that can be generated by PCR using the oligonucleotides of SEQ ID NO: 46 and 47, wherein the PCR is performed under any conditions with any DNA template. The scope of these claims is not commensurate with the enablement provided by the disclosure with regard to the large number of polypeptides encompassed. Predictability of which steps and reagents can be used to obtain polynucleotides encoding the desired polypeptides requires a knowledge of, and guidance with regard to which of the essentially unlimited number of possible sources for DNA and large number of conditions can be used in PCR with SEQ ID NO: 46 and 47 to generate polynucleotides encoding polypeptides with α-2,3-sialytransferase or dual α-2,3-sialytransferase/α-2,8-

sialytransferase activity. However, in this case the disclosure is limited to the polypeptide of SEQ ID NO: 3, as encoded by the polynucleotide of SEQ ID NO: 2.

While PCR methods as well as techniques for expressing the encoded protein and testing for α-2,3-sialytransferase and α-2,8-sialytransferase activity are known, it is not routine in the art to amplify DNA from an essentially unlimited number of sources under a large number of conditions and then test all of the encoded proteins for α-2,3-sialytransferase and α-2,8-sialytransferase activity, as encompassed by the instant claims. Furthermore, the DNA, conditions, and reagents to be used with a reasonable expectation of success in obtaining the desired generation of sialytransferase-encoding polynucleotides are limited and may be unpredictable (Kramer and Coen, 2001). In addition, one skilled in the art would expect any tolerance to modification of a successful method for generating a desired polynucleotide to diminish with each further and additional modification of reagents, steps, and DNA sources used.

The specification does not support the broad scope of Claim 43 which, encompasses all polypeptides comprising a sequence with α-2,3-sialytransferase activity, wherein the sequence is encoded by any polynucleotide that can be generated by PCR using the oligonucleotides of SEQ ID NO: 46 and 47, wherein the PCR is performed under any conditions with any DNA template. The specification does not support the broad scope of Claim 44 which, encompasses all polypeptides comprising a sequence with dual α-2,3-sialytransferase/α-2,8-sialytransferase activity, wherein the sequence is encoded by any polynucleotide that can be generated by PCR using the oligonucleotides of SEQ ID NO: 46 and 47, wherein the PCR is performed under any conditions with any DNA template. The specification does not support the broad scope of Claims 43 and 44

because the specification does not establish: (A) which DNA templates, from which sources, can be used to successfully generate α-2,3-sialytransferase- or dual α-2,3-sialytransferase/α-2,8-sialytransferase-encoding polynucleotides; (B) the PCR conditions to be used for generating polynucleotides encoding the desired polypeptides; (C) a rational and predictable scheme for choosing which DNA templates and conditions to use; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices of DNA templates and PCR conditions are likely to be successful in generating polynucleotides encoding the desired polypeptides.

Since Claim 46 recites the polypeptide of Claim 43 further comprising a peptide tag, Claim 46 is also rejected under 35 U.S.C. 112 first paragraph due to lack of enablement for the same reasons discussed above.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any number of polypeptides comprising any sequence having α-2,3-sialytransferase- or dual α-2,3-sialytransferase/α-2,8-sialytransferase activity, wherein the sequence is encoded by any polynucleotide that can be generated by PCR using the oligonucleotides of SEQ ID NO: 46 and 47, wherein the PCR is performed under any conditions with any DNA template. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of the identity of the FXR-mediated actions and methods of repressing said actions having the desired biological characteristics is unpredictable and the experimentation left to those skilled in

the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Written Description

Claims 43, 44, and 46 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

These claims are directed to a genus of polypeptides comprising any sequence having α-2,3-sialytransferase or dual α-2,3-sialytransferase/α-2,8-sialytransferase activity, wherein the sequence is generated by PCR, under any conditions, using the oligonucleotides of SEQ ID NO: 46 and 47 and any DNA template. The specification teaches the structure of only a single representative species of such polypeptides. Moreover, the specification fails to describe any other representative species by any identifying characteristics or properties other than the functionality having α-2,3-sialytransferase or dual α-2,3-sialytransferase/α-2,8-sialytransferase activity and being encoded by any polynucleotide that can be generated by PCR, under any conditions, using the oligonucleotides of SEQ ID NO: 46 and 47 and any DNA template. Given this lack of description of representative species encompassed by the genus of the claim, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicants were in possession of the claimed invention.

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims,

Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

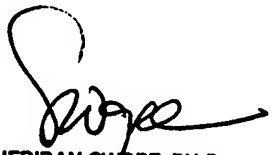
It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sheridan Lee Swope, Ph.D.
Art Unit 1656



SHERIDAN SWOPE, PH.D.
PRIMARY EXAMINER